(CSIR) to undertake a comprehensive review of the drugs regulatory system in the country including the problem of spurious and substandard drugs and recommend remedial measures to deal with this problem effectively. The Government has intiated steps to study the measures recommended in the report submitted by the expert committee.

Side effects of drugs

1272. SHRI EKANATH K. THAKUR: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that the pharmaceutical companies in the country fail to update doctors on new side effects of widely used drugs by not updating the information on package inserts;

(b) whether it was found that though product insert serve as a guide to the prescribe and the patient, there is no mention of last update and also on warnings issued by the drug regulators like the USFDA; and

(c) if so, the steps Government propose to take to emphasize on updates by pharmaceutical companies to ensure the safety of patients?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) to (c) While granting the New Drug approval, under Rule 122 A/B, the pharmaceutical companies are required to follow the condition regarding adaptation of package insert, carton & label. Also the company has to state if any restriction have been placed on the use of drug in any other country e.g. dosage limit, exclusion of certain age group, warning about adverse drug reaction etc. as per item 10 in Schedule Y of Drugs and Cosmetics Rules.

It is however, the responsibility of drug manufactures to keep the Medical Community informed about the side effects of drug marketed by them and also to update their package insert and product information regularly.

The package insert is issued by Doctors in order to ensure that prescription drug information is balanced and accurately communicated.

Precautions or restriction concerning use of some drugs have been issued from time to time like for Paracetamol, Ciapride, and Minoxidil and Phenylpropenylamin (PPA) etc.

Safety standards for packaged food/bottled water

1273. SHRI R.P. GOENKA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the steps being taken to ensure that safety standards are met by packaged food/bottled water industries, in view of frequent revelations by media of safety hazards of the same, as in the case of a prominent chocolate manufacturer;

(b) the norms being followed in the country *vis-a-vis* those followed internationally and the details thereof; and

(c) the reason for Government feeling shy of punishing the culprits?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) to (c) The provisions of PFA Act, 1954 and Rules made there under are being implemented by the State/UT Governments and these Governments have been requested from time to time to check the quality of all food products and initiate action as per the provisions of PFA Act, 1954. The State Governments are drawing samples of all food products including chocolates under the PFA Act, 1954.

The safety standards for packaged food/packaged water are notified by the Government of India based on the recommendations of CCFS. Efforts are being made to gradually harmonize the standards for food products with those of codex/international norms.

Reduction in prices of Anti-retrovirus drugs

1274. SHRI DINA NATH MISHRA:
SHRI R.K. ANAND:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government have finalized modalities for price reduction